510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter Information and Preparation Date

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Wilmington, DE 19810
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Prepared: March 6, 2014

2) Device Name, Common Name, and Classification Name

Proprietary Name

Halo Medical Technologies, Catalyst™, MidCRYSTL™, HALO™ Ultrasound System

Common/Usual Name

Diagnostic Ultrasound System and Accessories

Classification Names

	CFR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the Predicate Device

The Laborie NuWav (AKA "AquaVU360) (K081781) is a comparable and substantially equivalent device. The Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System Transducer Probes are produced by the same OEM manufacturer, and the system has the same technological characteristics, safety and effectiveness features, design features, and comparable intended uses and basic operating modes.

4) Subject Device Description

The Halo Medical Technologies, Catalyst™, MidCRYSTL™, HALO™ Ultrasound System is a self contained portable, single-mode, and single-application ultrasound imaging system. The system contains an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface and control offering a full complement of conventional operating modes, software-based parameter controls, and video recording.

User-customized parameter settings for the MidCRYSTL™ Endoanal, HALO™ Endovaginal and HALO™ Surface Ultrasound Probes may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit power, images controls selection, and Time Gain Compensation (TGC). Controls are also provided to select display format and to utilize the cine function.

More detailed explanations of these functions and controls are included in the User Manuals, and in the software/firmware documentation included in this 510(k) Notification. Patient contact materials have been used in accordance to their intended use and are described below for each individual transducer. The transducers were previously cleared for use on other Systems (K951976 and

referenced in K070907).

The Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System is a B-Mode ultrasound scanner which provides high resolution, high penetration performance. Probes are supported in frequencies from 3.5 MHz to 24.0 MHz. The probes are indicated expressly for endoanal, endovaginal, and/or abdominal/transperineal (surface) application.

The Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System provides various measuring functions. It can measure distances and calculate angles. Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System supports the Cine function (capable of storing up to 512 sequential images). Management of patient history is possible by image-storage function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing. The same clinical uses were cleared for the predicate device(s), Laborie NuWAV (K081781).

5) Intended Use

"Catalyst" is a diagnostic ultrasound system designed to be used for investigating disorders of the pelvic floor. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. MidCRYSTL and HALO probes allow for ultrasonography of the following: 1) on the surface of the perineum and/or abdomen, 2) endocavity, by inserting the endovaginal probe into the vagina, and 3) endocavity, by inserting the endoanal probe into the anal canal.

6) Technological Characteristics

This device has the same technological characteristics (i.e., materials, image display, energy source, design, and acoustic output limits) as the predicate device.

6.a.) Technological Comparison Summary of Subject and Predicate Devices

Technological Characteristics		**Subject Device: Halo Medical Technologies, Catalyst™, MidCRYSTL™, HALO™ Ultrasound System**	**Predicate Device: Laborie Medical Technologies, NuWav Ultrasound System (K081781)**
Materials	Lens	TPX brand Polymethyle Pentene(PMP)	TPX brand Polymethyle Pentene(PMP)
	Housing	Ertalyte brand Polyetheylene Terephthalate (PET-P)	Ertalyte brand Polyetheylene Terephthalate (PET-P)
Display Mode		2-D, LCD monitor (256 gray shades)	2-D, LCD monitor (256 gray shades)
Measurements		Distance (mm), Angle (%)	Distance (mm), Angle (%)
Principle of Operation		Apply high voltage bursts to Piezo-electric material in the transducer and detect the reflected echo to construct 2D images for diagnostic purposes.	Apply high voltage bursts to Piezo-electric material in the transducer and detect the reflected echo to construct 2D images for diagnostic purposes.
Transducer Probe Design		Mechanical sector ultrasound imaging probe that connects directly to host computer via Universal Serial Bus (USB). Host computer forms real-time ultrasonic images of human tissue without need for additional electronics, power supplies, or support devices of any kind.	Mechanical sector ultrasound imaging probe that connects directly to host computer via Universal Serial Bus (USB). Host computer forms real-time ultrasonic images of human tissue without need for additional electronics, power supplies, or support devices of any kind.
Acoustic Output Limits: All Applications		$I_{SPTA.3}$ 94 mW/cm2 (Maximum) MI 1.9 (Maximum)	$I_{SPTA.3}$ 94 mW/cm2 (Maximum) MI 1.9 (Maximum)

6.b.1.) Summary of Nonclinical Tests and Standards Used

Substantial equivalency to the predicate device has been demonstrated through the following nonclinical tests and standards referenced in this 510(k) submission:

- Acoustic Output Measurement, conducted in accordance with the AIUM/NEMA UD-2 and UD-3 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

- Product Safety and EMC Requirements for Medical Equipment:
  - Electrical Safety, IEC 60601-1
  - Electromagnet Compatibility, IEC/EN 60601-1-2
  - Ultrasound Equipment Safety, IEC 60601-2-37
    - Includes Thermal Safety Validation

- Biological Safety
  - ISO 10993-1 Compliant, Selection of Tests
  - ISO 10993-5 Compliant, Cytotoxicity Study using ISO Elution Method
  - ISO 10993-10 Compliant, ISO Vaginal Irritation Study and ISO Maximum Sensitization Study – Extract
  - ISO 10993-12 Compliant, Sample Preparation

6.b.2.) Summary of Clinical Tests

The subject of this premarket submission, the Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System, did not require clinical studies to support substantial equivalence.

6.b.3.) Conclusions

Halo Medical Technologies considers the Catalyst™, MidCRYSTL™, HALO™ Ultrasound System to be as safe and effective as the predicate device(s). The performance of the subject device is substantially equivalent to the predicate device(s).

Intended uses and other key features are consistent with traditional clinical

practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with medical device industry standards. The device conforms to applicable medical device

safety standards and compliance is verified through independent evaluation. Diagnostic ultrasound has accumulated a long history of safe and effective performance.

Therefore, it is the opinion of Halo Medical Technologies that the Catalyst™, MidCRYSTL™, HALO™ Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 5, 2014

HALO Medical Technologies, LLC
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
BUFFALO MN 55313

Re: K140899
Trade/Device Name: Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: April 7, 2014
Received: April 8, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Halo Medical Technologies Catalyst™, MidCRYSTL™, HALO™ Ultrasound System, as described in your premarket notification:

Transducer Model Number

ER/12 MHz/ES 12MHz GP 3.5 MHz/AB 3.5 MHz EC 7.5 MHz/EB 7.5 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140899

Device Name

Halo Medical Technologies, Catalyst™, MidCRYSTL™, HALO™ Ultrasound System

Indications for Use *(Describe)*

"Catalyst" is a diagnostic ultrasound system designed to be used for investigating disorders of the pelvic floor. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. MidCRYSTL and HALO probes allow for ultrasonography of the following: 1) on the surface of the perineum and/or abdomen, 2) endocavity, by inserting the endovaginal probe into the vagina, and 3) endocavity, by inserting the endoanal probe into the anal canal.

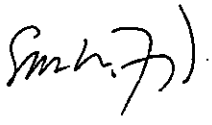
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

System: **Halo Medical Technologies, Catalyst™ Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						Note 1
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)	N						Note 2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						
	Trans-vaginal	N						
	Trans-urethral							
	Trans-esoph. (non-card.)							
	Muscular-Skeletal (Conventional)							
	Muscular-Skeletal (Superficial)							
	Intravascular							
	Invasive Diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)							
	Retroperitoneum							
	Female reproduction system and fetus (transcutaneous)							
	Superficial structures & pathologies							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N=New Indication
Note 1: Abdominal, Solid Organs, Aneurysms, Bladder
Note 2: Small Organ, Testes, Prostate

☒ Prescriptive Use (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Diagnostic Ultrasound Indications for Use Form

Transducer: ER/12 MHz/ES 12MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-card.)							
	Muscular-Skeletal (Conventional)							
	Muscular-Skeletal (Superficial)							
	Intravascular							
	Invasive Diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)							
	Retroperitoneum							
	Female reproduction system and fetus (transcutaneous)							
	Superficial structures & pathologies							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N=New Indication

☒ Prescriptive Use (Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Diagnostic Ultrasound Indications for Use Form

Transducer: GP 3.5 MHz / AB 3.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						Note 1
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)	N						Note 2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-card.)							
	Muscular-Skeletal (Conventional)							
	Muscular-Skeletal (Superficial)							
	Intravascular							
	Invasive Diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)							
	Retroperitoneum							
	Female reproduction system and fetus (transcutaneous)							
	Superficial structures & pathologies							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N=New Indication
Note 1: Abdominal, Solid Organs, Aneurysms, Bladder
Note 2: Small Organ, Testes, Prostate
☒ Prescriptive Use (Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Diagnostic Ultrasound Indications for Use Form

Transducer: EC 7.5 MHz / EB 7.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
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N=New Indication

☒ Prescriptive Use (Part 21 CFR 801 Subpart D)

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